

Notice of Allowability

Application No.

09/543,268

Examiner

Paul B. Prebilic

Applicant(s)

BOYCE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed June 17, 2004.
2. ☒ The allowed claim(s) is/are 1-6, 9-18, 21, 24-26 and 30-35.
3. ☒ The drawings filed on 05 April 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

*Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Dilworth on September 1, 2004.

The application has been amended as follows:

1. (Currently amended) An osteoimplant consisting essentially of a solid aggregate of superficially demineralized bone-derived elements bonded to each other through covalent chemical linkages between their surface-exposed collagen formed by chemical linkages, wherein the chemical linkages are formed by a chemical crosslinking agent, and wherein the solid aggregate of bone-derived elements possesses a compression strength of from about 10 to about 200 MPa, said elements made from bone particles superficially demineralized such that they retain a high proportion of their original mineral content.

In claim 2, line 3, after "xenogenic", a comma ---,--- was inserted.

In the title, the language "AND METHOD OF ITS MANUFACTURE" was deleted.

The following is an examiner's statement of reasons for allowance:

Upon review of the claims filed June 17, 2004 and the prior art of record, the Examiner concluded that the mineral content of the bone particles was a key distinction over the prior art of record. It was determined that normal adult bone has a mineral

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content of about 67% by weight (Stedman's Medical Dictionary, 23rd Edition (1976), page 187). In addition, to obtain the claimed compression strength, Applicants state that the bone-derived elements must retain a high proportion of their original mineral content; see page 9, first full paragraph of the present specification. For these reasons, the Examiner concluded that the percent mineral content of bone particles having a high proportion of their original mineral content would be much higher than 2 to 4% by weight or less than 5% as in the demineralized bone particles of the prior art. Therefore, the claims are not rendered obvious by Wolfinbarger (US 6,189,537), as a teaching for the Lyle patent (US 5,061,286), because Wolfinbarger teaches demineralization down to the 2% to 4% range; see Wolfinbarger's abstract and column 13, lines 23-40.

In addition and in consideration of Applicant's remarks filed June 17, 2004, the Examiner changed his position with regard to the 37 CFR 1.131 affidavit filed October 1, 2003 and concluded that it was sufficient to show earlier invention. In particular, the 9 day period of inactivity was considered reasonable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic".

Paul Prebilic
Primary Examiner
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